

REMARKS

Status of the claims

Claims 3 and 5-11 are currently pending and under examination. No new amendments have been introduced into the claims in this paper.

Rejection under 35 U.S.C. § 103

Claims 3 and 5-11 are rejected as allegedly unpatentable over Pavlakis *et al.*, U.S. Patent No. 5,965,726 ("Pavlakis"), in view of Myers *et al.*, Human Retroviruses and AIDS 1995 ("Myers") and Benson *et al.*, *J. Virol.* 72:4170-4182, 1998 ("Benson"). The Examiner characterizes Pavlakis as disclosing a detailed method for the elimination of inhibitory/instability regions in the HIV-1 *gag* gene. Myers is characterized in the office action as teaching prototypical nucleotide sequences of the *gag* gene from various HIV-2 and SIV isolates including SIVmac239; and Benson is characterized in the rejection as teaching pharmaceutical compositions comprising recombinant constructs encoding SIV *gag* and demonstrating that the compositions are useful to inhibit viral replication in macaques. The Examiner alleges that it would have been *prima facie* obvious to extend the teaching of Pavlakis to prototypical SIV isolates, as described by Myers, to identify similar INS regions in SIV *gag* genes. The Examiner further contends that one of skill would have been motivated to modify these regions to make an SIV *gag* mRNA that can be expressed more efficiently and to include such a modified *gag* gene in a vaccine vector, such as the vector described by Benson. Applicants respectfully traverse.

The facts of the present rejection are analogous to the facts of an improper obviousness rejection applied in *In re Deuel*, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995) ("Deuel"). In *Deuel*, the Federal Circuit found improper the rejection of claims reciting specific nucleic acid sequences as obvious over the combination of two references, the first that provided a partial amino acid sequence and the second that provided a method of cloning nucleic acid sequences. The Federal Circuit stated that "focus on known methods for potentially isolating the claimed DNA molecules is also misplaced because the claims at issue define compounds, not methods." *Deuel*, 34 U.S.P.Q.2d at 1215. The court made it clear that the existence of a general method of

isolating the claimed DNA “is essentially irrelevant to the question whether the specific molecules themselves would have been obvious.” Id. Instead, it is necessary that the prior art render the biomolecule itself obvious.

In the present rejection, the Examiner has rejected claims reciting a specific nucleotide sequence identifier number as obvious over Pavlakis and the cited secondary references. As in Deuel, the Examiner in the present rejection has not cited a reference that teaches or suggests the specifically claimed nucleic acid sequence, but instead has improperly rejected the claims based on the alleged obviousness of a method of removing INS from a *gag* gene. Although Pavlakis provides teachings for successfully removing INS, Pavlakis does not teach making all of the specific nucleotide substitutions (see, the comparison of the mutated SIV *gag* to the wildtype SIV *gag* provided in Figure 4, which shows many, many substitutions) to obtain the precise modified SIV *gag* gene that is claimed here. The method of Pavlakis thus does not render obvious the sequence of this composition itself.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection.

CONCLUSION

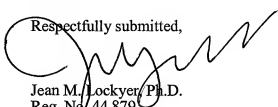
Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Appl. No. 10/644,027
Amdt. dated February 23, 2009
Reply to Office Action of August 21, 2008

PATENT

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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